

Morges, Switzerland) is polymer- and carrier-free, releases Biolimus A9 into the vessel wall over a period of 4 weeks, and then technically becomes a BMS.

**Methods** 2,466 pts at high bleeding risk from 68 centers in Europe, Asia, and Canada were enrolled over an 18 months period in a double-blinded randomized 1:1 comparison of the Gazelle™ BMS vs. the BioFreedom DCS (both Biosensors, Morges, CH) with a 1 month course of DAPT only in both arms. At 1 year, the primary endpoints are: safety: a composite of cardiovascular death, MI and stent thrombosis, and efficacy: the rate of ci-TLR.

**Current results** In the trial population, the most frequently used inclusion criteria were: advanced age (64%), need for long term oral anticoagulation (36%), anemia, recent bleeding or transfusion (20%), renal insufficiency (18%), planned surgery (15%) and concomitant cancer (9%). When compared to those included in 'all-comer' trials, pts were markedly older (75 years) and had more co-morbidities (diabetes 33%, atrial fibrillation 33%, peripheral vascular disease 15%, heart failure 13%, prior stroke 9% and COPD 11%) 1.5 lesions/pts were treated and 1.7 stents/pts were implanted for a total stent length of 32mm/patient. Technical procedure success was 95%. 71% of pts were discharged on DAPT alone, 27% of DAPT+oral anticoagulation and 2% on a single antiplatelet agent + oral anticoagulation.

**Conclusion** The trial focuses on a never previously studied high bleeding risk population characterized by advanced age and more comorbid conditions. It is the 1st evaluation of a DCS with clinical endpoints and comprises the shortest ever DAPT course with an active stent to be evaluated for both safety and efficacy.

*The author hereby declares no conflict of interest*

## 0197

### Angiographically visible distal embolization is not linked with culprit lesion but with clinical characteristics

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Despite the recent improvements in percutaneous coronary intervention (PCI), angiographically visible distal embolization (AVDE) complicates 6 to 18% of ST elevation myocardial infarction (STEMI) treated with PCI, and is associated with poor clinical outcomes. Culprit lesion characteristics have been proved to be the main predictive factor of AVDE. But data regarding clinical characteristics predicting AVDE are lacking. We aimed to identify predictors of AVDE complicating PCI in STEMI management. 769 consecutive patients admitted for STEMI who underwent PCI were included. Clinical, angiographic and therapeutics characteristics were assessed for each patient. AVDE was defined as an abrupt vessel closure occurring at any point during the PCI procedure and that was not present at baseline. Thrombectomy was used only when thrombolysis in myocardial infarction flow was  $\leq 2$ . AVDE occurred in 112 (14.5%) patients. Patients with AVDE were older ( $67 \pm 14$  vs.  $63 \pm 14$ ; with  $p=0.010$ ), less likely to be men (59 vs. 74%; with  $p=0.002$ ), have more frequently an artery diameter  $>3$ mm (36 vs. 28%; with  $p=0.046$ ), a right coronary artery culprit lesion site (59 vs. 37%; with  $p<0.001$ ) and more frequent thrombectomy (53 vs. 43%, with  $p=0.045$ ). There was no difference regarding the other cardiovascular risk factors neither regarding syntax score. By multivariate analysis, age  $>60$  (OR[95% CI]: 1.69 (1.09-2.64);  $p=0.020$ ), female gender (OR[95% CI]: 1.71 (1.09-2.70);  $p=0.020$ ), thrombectomy (OR[95% CI]: 1.67 (1.10-2.53);  $p=0.016$ ) and the right coronary artery culprit lesion site (OR[95% CI]: 2.52 (2.16-3.81);  $p<0.001$ ) were independent factors associated with AVDE. AVDE complicating PCI in STEMI management is frequent (14.5%). Strikingly we found no association between AVDE and culprit lesion characteristics. Conversely, clinical characteristics as age ( $>60$  year-old), female gender, thrombectomy and the right coronary artery culprit lesion site are the most powerful predictive factors of AVDE.

*The author hereby declares no conflict of interest*

## 0453

### Incidence of radiation-induced skin lesions after percutaneous coronary intervention

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**Background** Percutaneous coronary interventions (PCIs) use significant doses of ionizing radiation, especially when treating complex lesions. Ionizing radiation may lead to adverse acute or delayed skin lesions in this setting, for which the incidence is not well known.

**Purpose** To assess the incidence of radiation-induced skin lesions following PCI.

**Methods** We conducted a prospective, observational, single-centre study on the incidence of radiation-induced skin lesions at 3-5 days (acute) and at 6 months (subacute) after PCI with a dose-area product (DAP)  $\geq 200$  Gy.cm<sup>2</sup>, between 1 January and 31 December 2013. Patients consenting to participate were given information on potential skin lesions and were interviewed at 5-7 days and at 6 months after the PCI.

**Results** 1168 PCIs were performed; the radiation dose was available for 937 patients. Of these, 102 underwent PCI with DAP  $\geq 200$  Gy.cm<sup>2</sup>. High body mass index (BMI; OR 6.2, 95% CI 2.8-13.9) and elective (vs emergency) procedures (OR 2.0, 95% CI 1.1-3.4) were independently associated with DAP  $\geq 200$  Gy.cm<sup>2</sup>. Three patients (3%, 95% CI 0.6-8.4) were diagnosed with acute lesions (DAP of 485 Gy.cm<sup>2</sup>, 205 Gy.cm<sup>2</sup>, and 201 Gy.cm<sup>2</sup>), two of whom also presented with subacute lesions following PCI with DAP of 485 Gy.cm<sup>2</sup> (Fig.) and 205 Gy.cm<sup>2</sup>. One patient presented with a subacute lesion (DAP 280 Gy.cm<sup>2</sup>) only. Four patients presented with a skin lesion, which represents 4% (95% CI 1.1-9.7) of patients with DAP  $\geq 200$  Gy.cm<sup>2</sup> and 0.4% (95% CI 0.1-1.1) of all the patients who underwent PCI, irrespective of DAP dose.

**Conclusions** The incidence of radiation-induced acute and subacute skin lesions developing after PCI in this single-centre study was 4% in patients with DAP  $\geq 200$  Gy.cm<sup>2</sup>, with a total incidence of 0.4%. These data may suggest the need for systematic assessment of skin lesions after high-dose radiation PCI.

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## 0107

### Radiation exposure of the operator during coronary interventions: comparison of right radial, left radial and right femoral approach

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**Background** Because of a presumably increased incidence of long-term malignancy in interventional cardiologists, radiation exposure of the operator (ORE) during coronary interventions is of rising concern. A few studies comparing femoral to radial or right to left radial access have been published, but no data comparing the three access sites are available to our knowledge.

**Purpose** We sought to compare ORE by right femoral (RFA), right radial (RRA) and left radial (LRA) access during percutaneous catheterization for diagnostic coronary angiography (CA) with or without coronary angioplasty (PCI).

**Methods** From September 2014 to February 2015, all consecutive patients undergoing elective or emergency CA/PCI were prospectively included. Selection of the access site was left to the discretion of the cardiologist. ORE was measured using individual electronic radiation dosimeter badges positioned externally on the sternum. Radioprotection materials and equipment was similar for all procedures. Primary endpoint was ORE quantified as cumulative dose (CD) per dose-area product (DAP), in order to adjust for the administered radiation dose.

**Results** In total 692 consecutive procedures, 386CA (56%) and 306PCI (44%) were performed, 380 (55%) via RFA, 232 (34%) via RRA and 80 (11%) via LRA. The CD was lower in the RFA ( $6.9 \pm 11.8 \text{ Sv}$  vs. RRA  $26.4 \pm 54.1 \mu\text{Sv}$ ,  $p < 0.001$ , vs. LRA  $9.9 \pm 18.5 \mu\text{Sv}$ ,  $p < 0.001$ ).

There was no difference in the DAP between LRA and RRA ( $34.4 \pm 23.8 \text{ Gy cm}^2$  vs.  $40.3 \pm 28.5 \text{ Gy cm}^2$ ,  $p = 0.13$ ).

The RFA demonstrated higher levels ( $55.3 \pm 64.3 \text{ Gy cm}^2$ ) compared to both RRA ( $p = 0.03$ ) and LRA ( $p < 0.01$ ).

The adjusted ORE was significantly lower in the RFA ( $0.17 \pm 0.27 \text{ Sv/Gy cm}^2$ ) compared to the RRA ( $0.62 \pm 0.69 \text{ Sv/Gy cm}^2$ ,  $p < 0.001$ ) or the LRA group ( $0.30 \pm 0.36 \text{ Sv/Gy cm}^2$ ,  $p < 0.001$ ), as was for the LRA compared to the RRA ( $p < 0.001$ ).

**Conclusions** The RFA in CA and PCI is associated with significantly lower ORE when compared to the RRA or LRA. The LRA is associated with significantly lower ORE when compared to the RRA.

*The author hereby declares no conflict of interest*

## 0254

### Updated reference levels for radiation doses to patients undergoing coronary angiography and coronary percutaneous interventions: the RAY'ACT2 study

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**Purpose** The RAY'ACT project is a nationwide, multicentre survey program aimed at evaluating patient radiation protection (RP) during coronary angiography (CA) and percutaneous coronary interventions (PCI) in French non-university public hospitals, which represent >30% of the national activity for PCIs, and 60% of the emergency cases. We present the updated reference levels based on the results of the second survey conducted in 2013 (RAY'ACT2).

**Methods** RP parameters from 48,547 CAs and 40,026 PCIs performed at 61 centres during 2013 and routinely registered in professional software were extracted and analysed retrospectively. Kerma-area product (KAP), fluoroscopy time (FT), number of acquired frames (Nb F) and runs (NR), and total Air Kerma at interventional reference point (KA, r) were analysed separately for CAs and PCIs (elective and ad hoc pooled). All procedures of the year were included.

**Results** The table shows the medians (Q1-Q3) of the RP parameters, updated RLs based on the 75th percentiles of the values for CA and PCI (bold), and previous RLs (RAY'ACT1, 2010).

**Conclusions** Between 2010 and 2013, a 20 to 30% decrease was observed in medians and Reference Levels (Q3) for main RP parameters, including KAP and total Air Kerma.

#### Abstract 0254 – Table: Results

	2013 (RAY'ACT2) 61 centres	2010 (RAY'ACT1) 44 centres
CA	N=48,547	N=31,066
KAP (Gy.cm <sup>2</sup> )	20.9 (11.8- <b>35.7</b> )	27.2 (15.5- <b>45.2</b> )
FT (min)	3.3 (2.1- <b>5.7</b> )	3.7 (2.3- <b>6.3</b> )
Nb Frames	404 (284- <b>566</b> )	553 (388- <b>769</b> )
KA,r (mGy)	294 (164- <b>498</b> )	421 (240- <b>695</b> )
PCI	N=40,026	N=25,356
KAP (Gy.cm <sup>2</sup> )	45.2 (25.6- <b>77.6</b> )	56.8 (32.8- <b>94.6</b> )
FT (min)	9.8 (6.3- <b>15.4</b> )	10.3 (6.7- <b>16.2</b> )
Nb Frames	676 (465- <b>960</b> )	837 (578- <b>1193</b> )
KA,r (mGy)	747 (421- <b>1285</b> )	1052 (589- <b>1788</b> )

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## 0368

### Radiation in transfemoral versus transradial access in diagnostic coronary angiography

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**Background/Introduction** Although transradial access (TRA) is being increasingly used in interventional cardiology, there are concerns about a possible increase in radiation exposure as compared to transfemoral access (TFA).

**Purpose** The aim of this study is the comparison of radiation exposure parameters between coronary angiography procedures performed via left radial artery, right radial artery or femoral artery and the detection of factors that contribute to increased radiation dose.

**Methods** We analysed collected data on radiation exposure for a total of 733 consecutive diagnostic coronary angiographies (69% in men) excluded those concerning patients with aortocoronary bypass grafts or those accompanied by aortography or ventriculography. Dose area product (DAP) and fluoroscopy time (FT) were used as a means of radiation exposure measurement.

**Results** The mean patients' age was  $66.8 \pm 10.1$  years and BMI  $28.4 \pm 4.6 \text{ kg/m}^2$ . Femoral access was used in 45% of the procedures, right radial access (RRA) in 42% and left radial access (LRA) in 13%.

More diagnostic catheters were used via TFA than TRA ( $2.24 \pm 0.63$  vs  $1.94 \pm 0.83$  respectively,  $p < 0.001$ ); LRA was associated with the use of more diagnostic catheters than RRA.

TRA was associated with increased FT ( $4.8 \pm 3.5$  vs  $3.1 \pm 2.4$  min,  $p < 0.001$ ) but there was no difference regarding FT between RRA and LRA. Hypertension and the presence of ascending aorta aneurysm were predictors of increased exposure parameters, especially in TRA, whereas diabetes mellitus was predictor of increased DAP. The use of 1 or 2 diagnostic catheters was associated with reduced DAP and FT.

**Conclusion** TRA is associated with increased FT. Hypertension and ascending aorta aneurysm are adversely affecting exposure parameters. With TRA and especially RRA is feasible the use of fewer diagnostic catheters in patients undergoing diagnostic coronary angiography.

*The author hereby declares no conflict of interest*

## 0570

### Association between low bone mineral density and coronary artery disease

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**Background** Many studies describe a relationship between brittle bones and cardiovascular disease.

The physiopathology may be explained by the osteoprogenitor (OPG) that protects the vascular wall and inhibits the RANK-RANKL system which is a strong inhibitor of osteoclasts. Thus it seems interesting to assess the prevalence of osteoporosis and osteopenia in patients with a confirmed coronary heart disease.

**Material and Methods** This study enrolled 46 patients who underwent a coronary angiography for chest pain. We identified two groups of patients:

– Group 1: patients with significant coronary artery disease.

– Group 2: patients with normal coronary angiography.

All patients had a physical exam, a phosphocalcic investigation and bone mineral density (BMD).

**Results** The mean age of the population was  $66.7 \pm 6.5$  years old. 52.17% were women. Among the 46 patients, 21.7% had an osteoporosis, 41.3% an osteopenia and 37% had a normal bone mineral density. 52% des 52% of the studied population had significant coronary artery disease, 48% had a normal coronary angiography. At the statistical analysis, prevalence of osteoporosis and osteopenia was significantly higher in group 1 than in group 2 ( $p < 0.001$ ).